REMARKS/ARGUMENTS

I. STATUS OF THE APPLICATION

Claims 219 – 272 have been withdrawn in response to the Office Action dated January 9, 2007, as being impermissibly switched. The January 9, 2007, Office Action invited Applicant to supply a correction responsive to the Office Action dated May 2, 2006. Therefore, claims 151-157, 159-170 and 174-210 are currently pending and stand rejected.

By way of this response, claims 151, 152, 153, 156, 159 and 204 have been amended. Claims 154-155 and 162-166 have been withdrawn without prejudice or disclaimer. Written support for the amended claims may be found at least at page 25 lines 17-20; page 31, lines 6-7, 16-17 and 11-20. Applicant respectfully submits that no new matter has been added by way of this amendment. No fees are believed due.

II. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

The Examiner states:

> The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.
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> * * *
>
> There is no evidence in the record that a composition meeting the ratio requirement without at least a therapeutically effective dose of omeprazole can achieve such a blood level. In addition, there is no evidence in the record that such blood level can be obtained when the drug to buffering agent ratio varied beyond the single 40 mg omeprazole-20 mg [sic] sodium bicarbonate composition.
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> * * *
>
> Nor was there any support that the wide varieties of basic agent of claim 161 would function in analogous manner in providing serum absorption as the 40 mg omeprazole/20 mg [sic] sodium bicarbonate coadministration.

In view of the present amendments, Applicant submits that this rejection is moot. Examples XV and XVI, at pages 91-110 of the specification, clearly describe and enable the claimed invention. One skilled in the art would be able to modify the teachings of the ranges in the disclosure to make and use the claimed invention. Claim 151 requires about 10 mEq to about 70 mEq of a buffering agent. The term "milliequivalents" or "mEq" inherently relates to the acid neutralizing capacity of a buffering agent and, therefore, the skilled artisan would certainly understand how to practice this element of the invention without undue experimentation. Further, the pharmacokinetic limitation ("average plasma concentration of the omeprazole of at least about 0.1 μg/ml at any time within about 30 minutes after administration") is a functional limitation, which is understood in the art and is permissible under applicable precedent. For example, in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 68 U.S.P.Q.2d 1865, 1873 (Fed. Cir. 2003), the Federal Circuit stated, "a functional limitation covers all embodiments performing the recited function." Here, although various buffering agents may differ by solubility (and hence rate of acid neutralization), the functional pharmacokinetic language limits the claim to those buffering agents (or mixtures thereof) that provide the claimed result. *See also In re Swinehart*, 169 U.S.P.Q. 226 (C.C.P.A. 1971). In light of the current amendments to the claims and the foregoing arguments, Applicant respectfully requests withdrawal of this rejection.

III. THE REJECTIONS UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN

According to the Office Action dated May 2, 2006, the claims are rejected under 35 U.S.C. § 102(b) as being anticipated by Carroll et al. ("Carroll"), U.S. Patent No. 5,447,918 ("McCullough"), WO 97/25066 ("Depui"), JP 05-255088 ("JP '088" or "Oishi") supplemented with Horowitz. The Office Action suggests that Carroll, McCullogh, Depui or Oishi anticipate "the claims with the dosage and base combination. The limitation of serum level within 30 minutes is the innate nature of such a composition as evidenced by Horowitz." In addition, the Office Action suggests that, "before tableting, a powder mixture/composition was in possession by the prior art."

Applicant hereby incorporates by reference its previous responses to similar rejections regarding the same references in its related patents and applications. Attached for the convenience of the Examiner are copies of the following:

1. Serial No. 09/901,942 (U.S. Pat. No. 6,645,988)—Amendment and Response to February 1, 2002 Office Action

2. Serial No. 10/260,132 (U.S. Pat. No. 6,780,882)—Declaration of Jeffrey O. Phillips dated July 14, 2003

3. Serial No. 10/418,410—Amendment and Response to Office Action dated December 23, 2005

4. Serial No. 09/481,207 (U.S. Pat. No. 6,489,346)—Amendment and Response dated June 25, 2001

5. Serial No. 90/007,686—Amendment and Response to Office Action dated March 24, 2006

Additionally, as admitted by the Examiner, Horowitz describes a liquid—not a powder for suspension as claimed—and the sodium bicarbonate component of Horowitz is far in excess than the buffering agent presently claimed.

For the foregoing reasons, Applicant submits that no *prima facie* case of anticipation has been established and respectfully requests withdrawal of this rejection.

IV. REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN

The Office Action of May 2, 2006, made a rejection under 35 U.S.C. § 103(a) over Carroll et al. ("Carroll"), U.S. Patent No. 5,447,918 ("McCullough"), WO 97/25066 ("Depui"), JP 05-255088 ("JP '088" or "Oishi") in view of Carroll, U.S. Patent No. 5,443,826 ("Borody") and Horowitz.

Applicant hereby incorporates by reference its previous responses (listed in Section III herein) to similar rejections regarding the same references in its related patents and applications.

Additionally, Borody is directed to administering a pharmaceutical composition comprising "a composition of fresh homologous faeces, equivalent freeze-dried and reconstituted faeces or a 'synthetic' faecal composition." Col. 4, ln 21-24. The composition may further contain omeprazole. Col. 4, ln 59-64. However, Borody fails to provide any teaching or suggestion of also employing a buffering agent—let alone about 5 mg to about 100 mg

omeprazole plus about 10 mEq to about 70 mEq buffering agent in an immediate release powder for suspension to provide the claimed plasma concentration.

For the foregoing reasons, Applicant submits that no *prima facie* case of obviousness has been established and respectfully requests withdrawal of this rejection.

V. OBVIOUSNESS-TYPE DOUBLE PATENTING

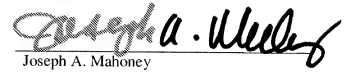
The claims stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the issued claims of U.S. 6,699,885; 6,645,988; 6,489,346; and 5,840,737 as described in the Office Action. Applicant will submit a terminal disclaimer upon the indication of allowable subject matter.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the pending claims are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,



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